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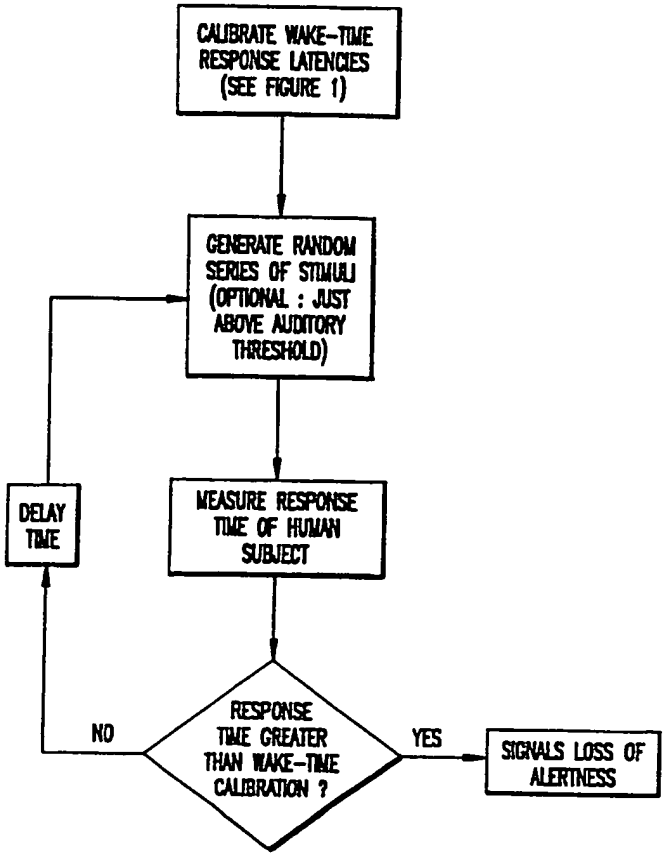
(54) Title: ALERTNESS MONITOR

(57) Abstract

The present invention monitors the alertness of a human subject by measuring and analyzing the response latency of the subject to a stimulus. The alertness monitor may consist of a non-intrusive, hand-held microswitch which a subject must press in response to a stimulus presented at random intervals. The stimulus may be either visual or auditory. The time required for the subject to press the microswitch in response to the stimulus determines the subject's response latency. The subject's response latency is then analyzed to determine whether the subject is sufficiently alert to continue the subject's activity. Response latencies that exceed a predetermined wake-time calibration of response latency signals a loss of alertness.



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ALERTNESS MONITOR

FIELD OF THE INVENTION

The present invention relates generally to a method and monitor for determining the alertness of a human subject and more particularly to a method and device for measuring and analyzing response latency to determine the alertness of a subject.

BACKGROUND OF THE INVENTION

Various occupations require the operation of equipment during all hours of the day and night. Increasingly, occupations are requiring the performance of tasks at times of the night where the tendency to fall asleep is at its greatest. In addition, many occupations involve conditions which require repetitive and monotonous operation that often have hypnotic effects. Such conditions are frequently observed, for example, in the operation of transportation vehicles such as the driving of motor vehicles on highways, the operation of trains, and in the flying of aircraft. Such conditions are also observed in the monitoring of control rooms by operators in the chemical, electronic, nuclear, and aerospace industries. Therefore becoming drowsy or even falling asleep is a common occurrence in many industrial, utility, and public service occupations that require around-the-clock and/or repetitive operation.

Because safety is of particular concern in most if not all occupations, some industries have implemented systems designed to determine whether or not employees are sufficiently alert to continue to safely operate a particular piece of equipment. Currently, there are two systems commonly used. The first, the so-called "dead-man's switch," relies on the principle that when an individual falls asleep, the individual loses muscle tone and thus will be incapable of maintaining a force on a

switch while asleep. A typical "dead-man's" switch is shown in U.S. Patent N . 4,617,559 to Slansky (the Slansky patent). The Slansky patent shows an alarm system having a pressure-controlled switch within a wrapper secured to a steering wheel. When the grip of the user becomes relaxed, (due to fatigue, for example) an alarm is sounded. Dead-man's switches such as the one shown in the Slansky patent have been used extensively on a worldwide basis. However, it has been found that train operators, for example, can maintain trains equipped with a dead-man's switch at full throttle even though they are no longer sufficiently alert to external signals such as red stop lights. There is also evidence that an individual can maintain a dead-man's switch in a depressed position even when they are technically asleep.

The second commonly used system is an alerter device. Alerter devices typically require continuous performance of secondary tasks while performing primary tasks such as operating machinery. Some alerter devices, such as the one shown in U.S. Patent No. 4,679,648 to Johansen, require an operator to actively respond to a stimulus, such as an auditory or visual stimulus, by pressing a button. Failure to respond to the stimulus results in the signalling of an alarm. An affirmative response to the stimulus is assumed to indicate that the operator is fully alert. Alerter devices have the advantage of demanding that an operator maintain a continual and anticipatory vigilant state in order to perform effectively. However, even when operators are very substantially drowsy (or technically asleep), they can often still react to such signals despite their impaired state of alertness. Furthermore, operating a motor vehicle or highly technical and complicated equipment in such an impaired state of vigilance can have dangerous and costly implications for human safety. Experiments have shown that normal subjects can often respond to stimuli even though they are no longer awake or are not sufficiently alert to safely operate equipment. For example, experiments conducted by the inventors of the present invention found that subjects are capable of responding to auditory stimuli an average of 40% of the time by pressing

a button even though they were in Stage 1 sleep. Generally, Stage 1 sleep is a condition of waning consciousness, characterized by one's ability to partially respond to external stimuli. More specifically, Stage 1 sleep is defined by a relatively low voltage, mixed frequency EEG with a prominence of activity in the 2-7 cps range. Stage I sleep tends to be of short duration, ranging from about 1 to 7 minutes. Stage I sleep, especially following wakefulness, is characterized by the presence of slow eye movements. Tonic EMG levels are usually below those of relaxed wakefulness.

Some subjects were found to be occasionally capable of responding to stimuli during Stage 2 sleep. Generally, Stage 2 sleep is a condition of altered consciousness with a greatly impaired to completely absent ability to respond to external stimuli. More specifically, Stage 2 sleep is defined by an EEG containing sleep spindles of frequency 12-14 cps and 0.5 seconds in duration and/or K-complexes also 0.5 seconds in duration. Stage 2 is also characterized by a diminished muscle tone as measured by EMG. Therefore, alerter devices that rely exclusively on the lack of a subject's response to a stimulus cannot assure that an operator is alert or awake.

It has also been found that operators tend to develop a spontaneous and rhythmic way of operating and monitoring alerter devices which permit correct operation even though the operator is at a low level of vigilance. In addition, experiments performed over fifty years ago (Loomis, Harvey and Hobart, "Electrical Potentials of the Human Brain," *Journal of Experimental Psychology*, p. 249-279 (1936)) clearly demonstrated that there is no precise moment of sleep onset. Rather, it has been found that there is a gradual decline in alertness. Conventional alerter devices do not take this into account and thus also suffer the disadvantage of failing to differentiate different levels of alertness of the human subject.

SUMMARY OF THE INVENTION

It is with this background in mind that the present invention was developed. The present invention not only overcomes the problems of the related devices and methods, but furthermore, has many features and advantages not previously achieved with known methods and devices for monitoring alertness. The present invention is directed to a method of monitoring alertness in human subjects, comprising the steps of: calibrating a wake-time response latency of the human subject to a stimulus, generating a series of stimuli, providing the generated series of stimuli to a human subject, detecting the response of the human subject to each stimulus in the series of stimuli, measuring the time interval between the occurrence of each stimulus of the generated series and the detected response of the human subject and comparing the measured time interval to the calibrated wake-time response latency to determine a level of alertness of the human subject. The method of the present invention may also comprise the step of determining the auditory threshold of the human subject in a working environment so that the stimulus provided to the human subject is an auditory stimulus slightly greater than the determined auditory threshold of the human subject in the working environment. In addition, the method of the present invention may also comprise the step of determining the variance of response latencies during the wake-time calibration to determine whether the human subject is deliberately slowly responding to each of the stimuli.

The present invention may also be directed to an apparatus for monitoring alertness in a human subject comprising means for generating a series of stimuli, means for providing the generated series of stimuli to the human subject, means for detecting the response of the human subject to each stimulus of the generated series of stimuli and means for measuring the time interval between the occurrence of each stimulus of the generated series of stimuli and the detected responses of the human subject and for comparing the measured time interval to a calibrated

wake-time response latency to determine the level of alertness of the human subject.

The present invention has a number of features and advantages not previously achieved with known methods and devices for monitoring alertness. One feature and advantage is that the method and device of the present invention differentiates between different levels of alertness of the human subject. In addition, utilizing laboratory data which indicates that the auditory threshold of a human subject rises after sleep onset, the present invention may incorporate the additional feature and advantage of providing an auditory stimulus just above the measured wake-time auditory threshold of the human subject to assist in monitoring the alertness of the subject. Yet an additional feature and advantage of the present is found in the option of generating a random series of stimuli which prevents the development of a spontaneous and rhythmic response by the operator to a stimulus. Yet another feature and advantage of the present invention is found in the individual calibration of the alertness monitor to the particular human subject.

Brief Description of the Drawings

The foregoing and other aspects and features of the invention will be more fully appreciated as the same becomes better understood when considered in conjunction with the detailed description of the present invention viewed with the accompanying drawings in which:

Figure 1 is a flowchart depicting the steps of calibrating a wake-time response latency according to the present invention; and

Figure 2 is a flowchart depicting the method of monitoring alertness of the present invention.

Detailed Description of the Preferred Embodiment

Referring now to the Figures, a preferred embodiment of the present invention is shown. The present invention comprises a method and apparatus for monitoring alertness of a human subject. As discussed in greater detail below, both the apparatus and its intended method of use are particularly useful in monitoring alertness of a human subject who is operating a piece of equipment or is performing some task by measuring and analyzing response latency to detect the alertness of the subject. The alertness monitor is preferably self-contained and ambulatory and, for example, could be used by automobile drivers. The output could also be attached to a recorder, such as a cockpit data logger on an airplane.

Turning to the flowcharts of Figures 1 and 2, the method of monitoring alertness of the present invention is shown. The method of monitoring alertness generally comprises four basic steps: calibrating a wake-time response latency, generating a series of stimuli, measuring a response time interval of a human subject to the series of stimuli and comparing the measured time interval to the calibrated wake-time response latency to detect a level of alertness of the human subject. Each of these steps will now be described in greater detail, with reference to the apparatus used to accomplish each particular step.

With reference to the flowchart of Figure 1, the method of calibrating the wake-time response latency will now be described. Because response rates differ markedly among individuals, it is often important to calibrate the response latency for the particular individual. The wake-time response latency is preferably determined when the subject is fully alert. A subject is considered to be fully alert when he/she is well-rested and is not under the influence of any drug. Initially, to determine a wake-time calibration, a series of stimuli are presented to the human subject. The stimuli may be either auditory or visual. In generating auditory stimuli, the findings of Mullin and Kleitman ("Variations and Thresholds of Auditory Stimuli Necessary to Awaken the Sleeper"

American Journal of Physiology (1938) pp. 477-41) and Bartlett ("Minimal Auditory Stimuli During the Onset of Sleep" *American Journal of Psychology,* (1941) pp. 109-112) may be used. These references are herein incorporated in their entirety by reference. These findings indicate that the auditory threshold of a subject rises after sleep onset. Therefore, the series of stimuli in this step of the present invention are preferably auditory stimuli at the auditory threshold of the human subject as measured in the working environment. More specifically, the series of stimuli are preferably auditory stimuli which are within the range of approximately 2-7 db and preferably approximately 5 db above the auditory threshold of the human subject in the working environment. The auditory threshold of the subject is determined by audiometric testing using any known technique. One example is to use a Beltone Model 10D audiometer. The working environment is defined as the environment in which the alertness monitoring of the human subject is to take place. Preferably, the series of stimuli are generated in a random manner although a systematic series of stimuli having a predetermined time interval between individual stimuli may also be used. The means for providing a series of auditory stimuli to the human subject is preferably a loudspeaker or other auditory device. In the alternative, devices capable of providing visual stimuli, such as a light bulb or other light source, may also be used alone or in combination with an auditory stimulus. For example, a soft tone followed by a visual flash may be used to alert the operator that the test is coming in the event that the operator is not positioned to take the test. The tone provides warning of the impending arrival of the flash stimulus or test.

In response to the series of stimuli, the human subject is required to respond in an affirmative manner. Preferably, a microswitch is used to elicit a response from the operator to each of the series of stimuli. In the alternative, any type of switch or other device which can detect a response from a human subject may also be used. A microswitch is defined as any switch that can be disposed adjacent the human subject so that there is a

minimal tim delay between the subject's perception of the stimulus and th affirmative response by the subject. For example, th switch could be integral with the equipment the operator is using such as a control panel or steering wheel. The time interval between each stimulus of the generated series of stimuli and the affirmative response of the human subject to each stimulus is used to determine a response time interval. The interval may be measured by a microcomputer or other time-measuring device such as a stop watch. Preferably, 12 response time intervals are measured to calibrate the average wake-time response latency although a greater or smaller number of responses could be measured. A suitable range of intervals may be between 4 and 16. To prevent the likelihood of an individual responding deliberately slowly in determining the wake-time response calibration (in order to avert being subsequently judged non-alert) a microcomputer can be used to perform multiple self-calibrations, accepting the wake-time calibration only if all of the responses are clustered in a narrow band. This is done because it is believed that individuals cannot deliberately be consistently slow (or fast) in responding to stimuli. If a subject fails this self-calibration, the calibration process is repeated. Once determined, the wake-time calibration can be stored in a computer memory device and used as a reference point to determine the level of alertness of the subject.

With reference to Figure 2, the remaining steps of the method of the present invention will now be described. The second step involves generating a series of stimuli and exposing the generated series to the human subject in the working environment (i.e., when the subject is operating a piece of equipment or performing a task). Preferably, the series of stimuli are presented in a random rather than a systematic manner (a fixed time interval between stimuli). The stimuli may be auditory, visual, or a combination of both as described above.

The third step of the method of the present invention requires an affirmative response from the human subject who is being monitored. Similar to step 1, a switch may be used to detect the response of the

human subject to the generated series of stimuli. As described above, a non-intrusive microswitch provided adjacent a finger of the human subject is preferred. The time between the onset of the stimulus and the subject's affirmative response is defined as the response time interval of the human subject.

The fourth step of the present invention is to compare the measured response time interval of step three to the calibrated wake-time response latency of step one to determine a level of alertness of the human subject. Preferably, this comparison is performed by a computer. If the measured response time interval of step three exceeds the prior wake-time calibration of step one by a predetermined duration a loss of alertness is detected. The predetermined duration is selected by considering, for example, the age and physical ability of the operator and the requirements of the task peformed. For example, the predetermined duration could be three standard errors above the calibrated average response latency (the standard error = standard deviation / (# responses)$^{1/2}$. The computer may also be used to disable an apparatus under the control of the operator, to awaken the operator or to summon supervisory personnel if the human subject being monitored is determined to be incapable of implementing the task. Following step four is a delay time during which no stimuli are generated, after which step one is repeated.

Table 1 shows experimental data collected by applicants. The data was accumulated by measuring the response latencies of six healthy human male subjects to sensory stimuli during various stages of alertness. Each subject had a small microswitch taped to the index finger of his dominant hand such that it could be comfortably pressed by the thumb. The subject was instructed to press the switch when the subject detected the stimulus. When auditory stimuli were used, the auditory stimuli were delivered at the auditory threshold of the particular human subject determined in the working environment while the subject was fully awake. Wakefulness and stages of sleep (Stage 1-4 and REM) were determined

by applying electrodes to the subject to measure the electroencephalogram, electromyogram and electroretinogram of the subject.

TABLE 1. RESPONSE LATENCIES OF SIX SUBJECTS TO SENSORY STIMULI

SUBJECT	WAKEFULNESS		STAGE 1 DROWSING		STAGE 2 SLEEP	
	VISUAL	AUDITORY	VISUAL	AUDITORY	VISUAL	AUDITORY
#1	439	417	904	839	1180	1488
#2	427	323	677	640	----	567
#3	438	436	584	727	1275	1350
#4	640	641	1160	993	1700	1050
#5	651	887	1184	1150	3067	1100
#6	602	661	826	1013	800	
AVERAGE	533	561	889	893	1604	1111

RESPONSE LATENCY = SECONDS X 10^{-3} (milliseconds)

During wakefulness, a total 675 visual stimuli were delivered to the subjects, of which 656 elicited responses. During polygraphically defined Stage 1 sleep, 684 visual stimuli were delivered of which 202 elicited responses. During Stage 2 sleep, 1,388 visual stimuli were delivered of which 11 elicited responses. A total of 576 auditory stimuli were delivered to all six subjects during wakefulness of which 526 elicited responses. During polygraphically defined Stage 1 sleep, 773 auditory stimuli were delivered or which 345 elicited responses. During Stage 2 sleep, 1261 auditory stimuli were delivered of which 26 elicited responses.

These results demonstrate that the subjects were able to respond to visual and auditory stimuli during both wakefulness and polygraphically defined sleep (Stage 1 and Stage 2). The results shown on the chart highlight the need to individually calibrate the wake time response latencies to schedule a regimen of stimuli that will accurately detect when an individual subject is alert. Where the response latency is greater during Stage 1 and 2 sleep than during wakefulness indicates that the alertness of the subject during Stage 1 and Stage 2 sleep is significantly impaired as compared to wakefulness. This was true for the majority of the subjects tested. However, subject #2 actually had a decrease in

response latency between stage 1 and stage 2 sleep; although still increased over the wakefulness response latency. Moreover, a comparison of the response latency of subject #2 to auditory stimulus during Stage 2 sleep is less than the response latency of subjects #4, #5 and #6 to a visual stimulus during wakefulness. However, subject #2 completely failed to respond to visual stimuli during Stage 2 sleep. Hence, if subject #2 were operating a motor vehicle during Stage 2 sleep, he might respond to a honking horn, but not to a stop sign or red light.

These results, together with other findings that a change in response rate during wakefulness, Stage 1 and Stage 2 sleep, demonstrate that sleep onset is a gradual transitional process characterized by a lengthening of reaction time and a decrease in response rate just prior to a cessation in responsiveness. Therefore, monitoring alertness based on a comparison of the latency between the occurrence of the stimulus and the response by the subject to the stimulus during wakefulness and during the desired test period is much more effective in detecting lapses of attention than devices based simply on the occurrence of a response to a stimulus or even the arbitrary latency response to a stimulus.

The principles, preferred embodiments, and modes of operation of the present invention have been described in the foregoing specification. The invention which is intended to be protected herein should not, however, be construed as limited to the particular forms disclosed, as these are to be considered illustrative rather than restrictive. Variations and changes may be made by those skilled in the art without departing from the spirit of the invention. Accordingly, the foregoing detailed description should be considered exemplary in nature and not limited to the scope and spirit of the invention as set forth in the attached claims.

What Is Claimed Is:

1. A method of monitoring alertness in a human subject, comprising the steps of:

calibrating a wake-time response latency of the human subject to a stimulus;

generating a series of stimuli;

providing said generated series of stimuli to said human subject;

detecting the response of said human subject to each stimulus of said generated series of stimuli;

measuring the time interval between the occurrence of each stimulus of said generated series and said detected response of said human subject; and

comparing said measured time to said calibrated wake-time response latency to determine a level of alertness of said human subject.

2. The method of claim 1 wherein said step of generating a series of stimuli comprises generating a random series of stimuli.

3. The method of claim 1, further comprising the step of generating an alarm signal when said measured time is greater than said calibrated wake-time response latency.

4. The method of claim 1, further comprising the step of disabling an apparatus under the control of said human subject when said measured time is greater than said calibrated wake-time latency.

5. The method f claim 1, further comprising the step of determining the auditory threshold of said human subject in a working environment.

6. The method of claim 5, wherein said stimulus is an auditory stimulus which is greater than the determined auditory threshold of said human subject in a working environment.

7. The method of claim 6 wherein said stimulus is between approximately 2-7 db above the determined auditory threshold of said human subject in a working environment.

8. The method of claim 1, wherein the step of calibrating a wake-time response latency comprises an individualized calibration tailored to said human subject.

9. The method of claim 8, wherein said step of calibrating a wake-time response latency comprises the steps of:

generating a series of stimuli;

providing said generated series of stimuli to the human subject;

detecting the response of said human subject to each stimulus of said generated series of stimuli;

measuring the time interval between the occurrence of each stimulus of said generated series and said detected response of said human subject; and

determining whether the human subject is deliberately responding slowly to said series of stimuli.

10. The method of claim 1 wherein said series of stimuli are auditory stimuli.

11. The method of claim 1 wherein said series of stimuli are visual stimuli.

12. The method of claim 1 wherein said series of stimuli are a combination of auditory and visual stimuli.

13. An apparatus for monitoring the alertness of a human subject, comprising:

means for generating a series of stimuli;

means for providing said generated series of stimuli to the human subject;

means for detecting the response of said human subject to each stimulus of said generated series of stimuli; and

means for measuring the time interval between the occurrence of each stimulus of said generated series of stimuli and said detected response of said human subject, and for comparing said measured time interval to a calibrated wake-time response latency to determine the level of alertness of said human subject.

14. The apparatus of claim 13, wherein said means for detecting the response of said human subject is a switch.

15. The apparatus of claim 14, wherein said switch is a microswitch.

16. The apparatus of claim 13, further comprising means for determining the auditory threshold of said human subject in a working environment.

17. The apparatus of claim 13, wherein said means for providing said generated series of stimuli is a light source.

18. The apparatus of claim 13, wherein said means for providing said generated series of stimuli is a speaker.

19. The apparatus of claim 15, wherein said means for generating a series of stimuli generates said stimuli in a random series.

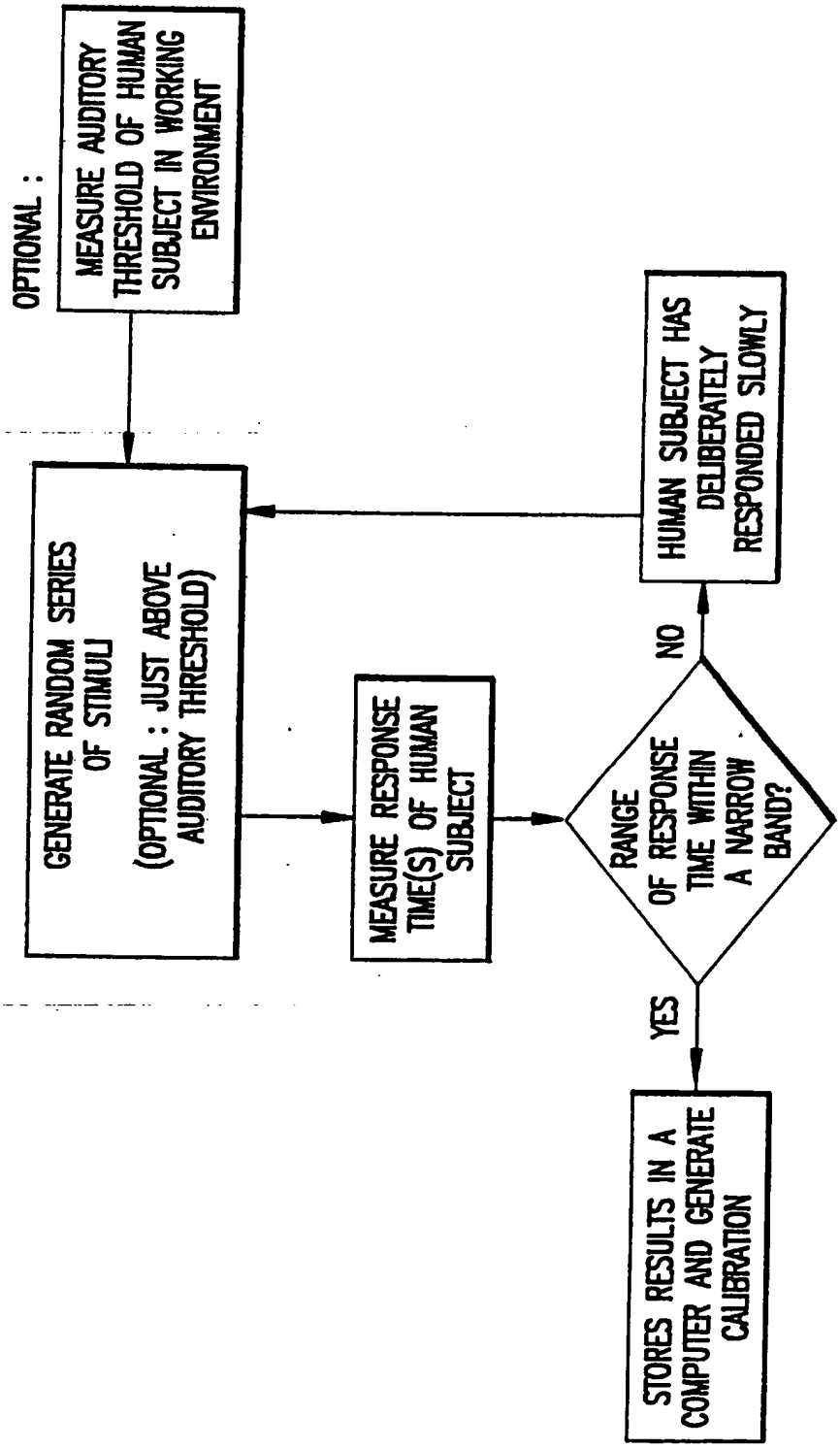
OPTIONAL :
MEASURE AUDITORY THRESHOLD OF HUMAN SUBJECT IN WORKING ENVIRONMENT
GENERATE RANDOM SERIES OF STIMULI
(OPTIONAL : JUST ABOVE AUDITORY THRESHOLD)
MEASURE RESPONSE TIME(S) OF HUMAN SUBJECT
RANGE OF RESPONSE TIME WITHIN A NARROW BAND?
NO
HUMAN SUBJECT HAS DELIBERATELY RESPONDED SLOWLY
YES
STORES RESULTS IN A COMPUTER AND GENERATE CALIBRATION

FIG. 1

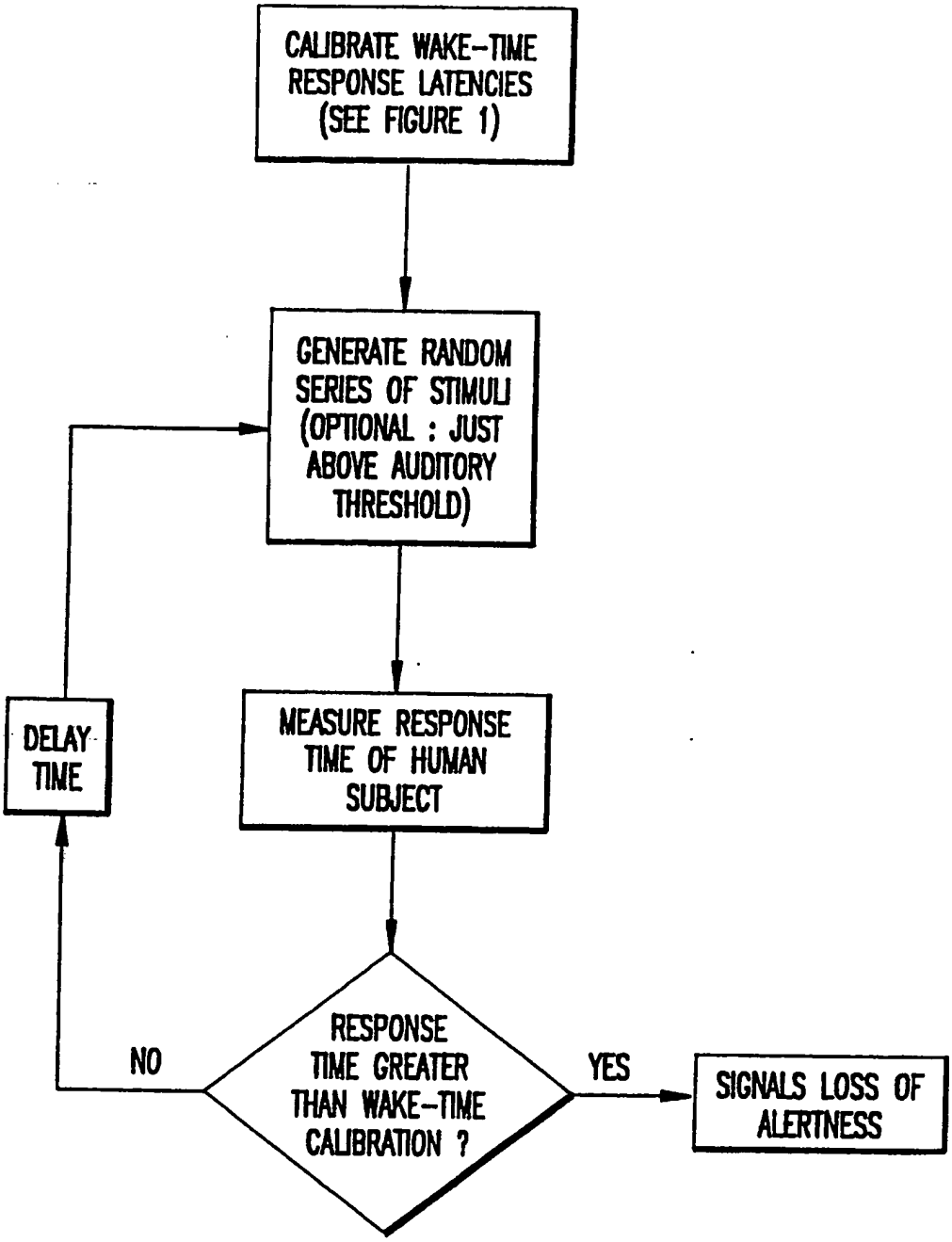
CALIBRATE WAKE-TIME RESPONSE LATENCIES (SEE FIGURE 1)
GENERATE RANDOM SERIES OF STIMULI (OPTIONAL : JUST ABOVE AUDITORY THRESHOLD)
MEASURE RESPONSE TIME OF HUMAN SUBJECT
DELAY TIME
RESPONSE TIME GREATER THAN WAKE-TIME CALIBRATION ?
NO
YES
SIGNALS LOSS OF ALERTNESS

FIG.2

INTERNATIONAL SEARCH REPORT

PCT/US92/09231

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 13/00
US CL :128/745, 746

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/745, 746, 741, 739, 742, 744; 340/501, 504, 527, 575, 573

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 3,922,665 (CURRY ET AL) 25 NOVEMBER 1975; See entire reference	1-19
Y	US, A, 4,201,225 (BETHEA, III ET AL) 06 MAY 1980; See entire reference	1-19
A	US, A, 3,761,921 (ADLER ET AL) 25 SEPTEMBER 1973; See abstract	1-19

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